

2013 (78 FR 45850). The regulations amends its regulations to provide optional notice procedures for processing rate filings by those natural gas pipelines that fall under the Commission's jurisdiction pursuant to the Natural Gas Policy Act of 1978 or the Natural Gas Act. The rule results in regulatory certainty and a reduction of regulatory burdens.

DATES: Effective September 30, 2013.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Need for Correction

On July 18, 2013, the Commission issued a "Final Rule, Order No. 781" in the above-captioned proceeding. *Revisions to Procedural Regulations Governing Transportation by Intrastate Pipelines*, 144 FERC ¶ 61,034 (2013).

This document serves to correct the table in Paragraph 82. Specifically, the last figure in the "total Annual Burden Hours" column is changed from "854" to "852".

Accordingly, in rule FR Doc. No. 2013-17822 published in the July 30, 2013 (78 FR 45850), on page 45861, in the table in paragraph 82, the entry in the "Total annual burden hours (a × b)" column for the entry "FERC-549 Total,"

the figure "854" is corrected to read "852".

Dated: August 21, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 524, 556, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Carprofen; Enrofloxacin; Florfenicol; Tildipirosin; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during June 2013. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective August 27, 2013.

FOR FURTHER INFORMATION CONTACT:

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Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during June 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (Freedom of Information Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

In addition, the animal drug regulations are being amended at 21 CFR 510.600 to correct a sponsor's name and at 21 CFR 556.733 to correct the acceptable daily intake of total residues of tildipirosin. This is being done to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JUNE 2013

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
200-524	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101.	Mupirocin Ointment 2%	Original approval as a generic copy of NADA 140-839.	524.1465	yes	CE. ¹
200-517	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408.	ZOBUXA (enrofloxacin) Flavored Antibacterial Tablets.	Original approval as a generic copy of NADA 140-441.	520.812	yes	CE. ¹
200-519	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408.	FLORVIO (florfenicol) 2.3% Concentrate Solution.	Original approval as a generic copy of NADA 141-206.	520.995	yes	CE. ¹
200-547	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin USP) plus TYLOVET 100 (tylosin phosphate) Type A medicated articles.	Original approval as a generic copy of NADA 141-276.	558.665	yes	CE. ¹

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JUNE 2013—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
200–555	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410.	LIBREVIA (carprofen) Soft Chewable Tablets.	Original approval as a ge- neric copy of NADA 141–111.	520.309	yes	CE. ¹

¹ The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 524, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for

“Purina Nutrition LLC”, and alphabetically add entries for “Piedmont Animal Health” and “Purina Animal Nutrition LLC”; and in the table in paragraph (c)(2), in the entry for “017800”, remove “Purina Nutrition” and in its place add “Purina Animal Nutrition”, and numerically add an entry for “058147” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address						Drug labeler code
*	*	*	*	*	*	*
Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410						058147
*	*	*	*	*	*	*
Purina Animal Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126–2910						017800
*	*	*	*	*	*	*
(2) * * *						
Drug labeler code						Firm name and address
*	*	*	*	*	*	*
058147	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410					
*	*	*	*	*	*	*

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.309 [Amended]

■ 4. In paragraph (b)(2) of § 520.309, remove “Nos. 000115, 055529, and

062250” and in its place add “Nos. 000115, 055529, 058147, and 062250”.

■ 5. In § 520.812, revise paragraphs (a) and (b) to read as follows:

§ 520.812 Enrofloxacin.

(a) *Specifications.* Each tablet contains:

(1) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(2) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) Nos. 000859 and 026637 for use of product described in paragraph (a)(1) of this section.

(2) No. 058198 for use of product described in paragraph (a)(2) of this section.

* * * *

§ 520.955 [Amended]

■ 6. In paragraph (b) of § 520.955, remove “No. 000061” and in its place add “Nos. 000061 and 058198”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1465 [Amended]

■ 8. In paragraph (b) of § 524.1465, add “026637,” after “025463,”.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 9. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.733 [Amended]

■ 10. In paragraph (a) of § 556.733, remove “10 micrograms” and in its place add “50 micrograms”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 11. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 12. In § 558.665, in the table, revise paragraph (e)(5) to read as follows:

§ 558.665 Zilpaterol.

* * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * *				
(5) 6.8 to provide 60 to 90 mg/head/day.	Monensin 10 to 40, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium</i> (Actinomyces) <i>pyogenes</i> .	As in paragraph (e)(1) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter.	000061 016592
* * * *				

Dated: August 19, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–20538 Filed 8–26–13; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9630]

RIN 1545–BK71

Use of Differential Income Stream as an Application of the Income Method and as a Consideration in Assessing the Best Method

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that implement the use of the differential income stream as a consideration in assessing the best method in connection with a cost sharing arrangement and as a specified application of the income method.

DATES: *Effective Date:* These regulations are effective on August 27, 2013.

Applicability Dates: For dates of applicability, see § 1.482–7(l).

FOR FURTHER INFORMATION CONTACT:

Mumal R. Hemrajani, (202) 622–3800 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

Final cost sharing regulations were published in the **Federal Register** (76 FR 80082) (REG–144615–02) (TD 9568) on December 22, 2011 (“final cost sharing regulations”). Corrections to the final cost sharing regulations were published in the **Federal Register** (77 FR 3606, 77 FR 8143, and 77 FR 8144) on January 25, 2012, and February 14, 2012. Certain guidance regarding application of the differential income stream approach was reserved in the final cost sharing regulations because the Treasury Department and the IRS believed it was appropriate to solicit public comments on that subject matter.

Temporary cost sharing regulations and a notice of proposed rule making on application of the differential income stream approach were published in the **Federal Register** (76 FR 80249 and 76 FR 80309) (REG–145474–11) (TD 9569)

on December 23, 2011 (“temporary and proposed regulations”). Comments were submitted, which we address in this Preamble. No request for a public hearing was received. The Treasury Department and the IRS are finalizing the proposed regulations without change.

Explanation of Provisions

The Treasury Department and the IRS were aware that some taxpayers were taking unreasonable positions in applying the income method by using relatively low licensing discount rates, and relatively high cost sharing discount rates, without sufficiently considering the appropriate interrelationship of the discount rates and financial projections. This practice gave rise to material distortions and the potential for PCT Payments not in accordance with the arm’s length standard. To address these problems, the temporary and proposed regulations provided additional guidance on evaluating the results of an application of the income method (§ 1.482–7T(g)(2)(v)(B)(2) (Implied discount rates) and (g)(4)(vi)(F)(2) (Use of differential income stream as a consideration in assessing the best method)), and